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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,199	12/21/2001	Claudio De Simone	2818-72	4379

7590 12/16/2003

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/024,199	<b>Applicant(s)</b> DE SIMONE, CLAUDIO	
	<b>Examiner</b> Deborah K. Ware	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 29, 2003, has been entered.

Claims 23-41 are presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 103***

Claims 23-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Cavaliere Vesely et al (A) in view of previously cited of record Cavaliere Ved. Vesely et al, and Ehret and newly cited Dobrogosz et al (B).

Claims are newly drawn to a method of potentiating activity of lactic acid bacteria, wherein at least one of the bacteria uses arginine, and method for treating infections and inflammatory conditions by combining lactic acid bacteria to provide for the portentiating activity effect.

Cavaliere (A), noted above and newly cited, teaches lactic acid bacteria can be combined with an agent compatible with the bacteria and capable of potentiating the activity of the combination of ingredients, note col. 5, lines 33-35.

Cavaliere Ved. Vesely et al and Ehret are discussed of record. Note specifically, of record that these previously cited references teach the combinations of lactic acid bacteria, effective amounts and that at least one lactic acid bacteria, *L. brevis* utilizes arginine.

Dobrogosz et al, newly cited above, teach lactic acid bacteria are capable of inhibiting microbial growth, see the abstract.

The claims differ from Cavaliere (A) in that arginine utilizing lactic acid bacteria are not specifically disclosed, nor are the specific combinations of bacteria.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to replace the bacteria and drug disclosed by Cavaliere (A) with hydrogen peroxide producing lactic acid bacteria as disclosed by Cavaliere Ved. Vesely et al and Ehret's arginine producing *L. brevis*, respectively, in order to potentiate the activity of the bacteria to provide for inflammatory infection treatment since as disclosed by Dobrogosz et al the lactic acid bacteria are capable of inhibiting microbial growth caused by inflammatory infections. Further, the treatment of vaginal areas as disclosed by the prior art would have been expected to provide successful results for other inflammatory infections of similarly related tissues, such as that found in a oral cavity. Also the inhibition of microbial growth is typically associated with deodorant activity. Each of the bacteria are clearly well known and the effective amounts are

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taught as well. Potentiating activity of peroxide-producing lactic acid bacteria by employing an arginine utilizing lactic acid bacteria is clearly taught, or at least suggested, by the newly presented combination of prior art. Therefore, the claims are *prima facie* obvious over the newly applied art rejection.

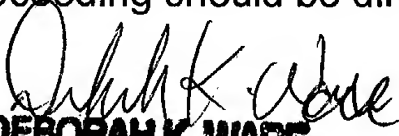
All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

  
**DEBORAH K. WARE**  
**PATENT EXAMINER**

Deborah K. Ware  
December 12, 2003